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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HU, HENRY S	
ART UNIT	**PAPER NUMBER**
1713	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,903	ANDERSSON ET AL.	
	Examiner	Art Unit	
	Henry S. Hu	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Election of February 16, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *22-27,29-39,42 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,28,40,41 and 43* is/are rejected.

7)☒ Claim(s) *17, 37 and 40-41* is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10 pages*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. It is noted that USPTO has received an **Election** filed on February 16, 2006. **Group I of Claims 1-21, 28, 40-41 and 43 was elected without traverse**. As pointed out earlier, the examiner **accepts Applicants' drawing in 18 sheets with 21 figures (Figures 1-21). Claims 1-44** with a total of **nine** independent claims (**Claims 1, 22, 26, 28, 29, 33, 36, 37 and 39**) are now pending, while **non-elected Claims 22-27, 29-39, 42 and 44 (Groups II-VIII) are all withdrawn from consideration.** An action follows.

Specification

2. The disclosure is objected to because of the following informalities:

(a) On **page 39** at line 24 and 32, **page 40** at line 14 and maybe throughout specification, the use of "D_3O" for the compound of 3,7-dimethyl-3-octanol is improper since it is not consistent with the same wording "**D3O**" used on page 23 at line 17 and page 14 at line 30.

(b) On **page 15** at line 14 and 32 and maybe throughout specification, the use of "Simma 2" is improper since it is not consistent with the same compound wording "**SiMMA2**" used on page 22 at line 12.

(c) On **page 41** at line 1, **page 43** at line 3 and maybe throughout specification, the use of "D30" is improper since it is not consistent with the same compound wording "**D3O**" used on page 23 at line 17 and page 14 at line 30.

Appropriate corrections are required.

Claim Objections

3. Claims 17, 37 and 40-41 are objected to because of the following informalities:

(a) On **Claim 17** at lines 1-3, the language of "comprises .... or ..." is improper. The Applicants need to check MPEP for correction. The use of "**is selected from ..... or ....**" or the MarKush language with "**is selected from the group consisting of .....and ....**" may be used to include any mixture..

(b) On **Claim 37** at line 3, recitation of "(b)" should be changed to **"(a)**".

(c) On **Claim 40** at lines 1-3, the language of "selected from the group consisting of .... And the metal salt is silver iodide" is very improper. The Applicants need to check MPEP for correction.

(d) On **Claim 41** at line 1, the language of "the lens formulation is Lens B" may be wrong according to MPEP since **the formulation of Lens B is a new matter, which is not supported on Claim 17 and Claim 18**.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. **Claims 1-21, 28 and 43 are** provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **Claims 1-7, 9 and 12-14** of copending Application No. **10/715,745 to Rathore et al. (USPG-PUB 2004/0151755 A1** with effective priority date 11-20-2000 and the same assignee).

This is a provisional obviousness-type double patenting rejection since the conflicting claims have not yet been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other. The subject matter claimed in the instant application is obviously disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Parent **Claim 1** of present application relates to **an antimicrobial ophthalmic lens comprising a metal salt** and **having a percent haze of less than 200%**, while parent **Claim 1 of 2004/0151755** relates to **an ophthalmic device** comprising a polymer and **ionized silver** in an initial concentration of at least about 10 ppm, wherein said ophthalmic device has a **haze of less than about 200%** and said silver releases from said ophthalmic device during use at rate with a rate constant, calculated using a first order kinetics equation, of up to about 1 $days^{-1}$.

It is noted that the open language of "comprising" is used in current Claim 1. An ionized silver is certainly included as one species in the genus of "metal salt" as known in the art for making ophthalmic lens or devices. Therefore, both pending applications are not patentably distinct and an **ODP rejection** is applied.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. *The limitation of parent* ***Claim 1*** *in present invention relates to* ***an antimicrobial ophthalmic lens comprising a metal salt*** *and* ***having a percent haze of less than 200%.*** *Other parent* ***Claim 28*** *relates to* ***a two-step method*** *of producing an antimicrobial ophthalmic lens comprising a metal salt. See other limitations of dependent* ***Claims 2-21, 40-41 and 43.***

8. Claims 1-21, 28, 40-41 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Rothore et al. (USPG-PUB 2004/0151755 A1 with effective US filing date of December 21, 2000).

Regarding the limitation of two parent **Claim 1 (composition) and Claim 28 (process of making), Rothore** et al. have disclosed the preparation of **an ophthalmic device having the percent haze at less than about 200%**. The lens comprises two components as: (A) a polymer and (B) an **ionized silver (or other types of metal salt**, see paragraph 34) in an initial concentration of at least 10 ppm (column 11, see Claim 1; abstract, line 1-7; see various types of silver salt on paragraphs 24 and 28-29). Rothore further discloses that such a device includes a contact lens, and certainly includes **an antimicrobial ophthalmic lens** (paragraphs 3 and 11). Rothore furthermore discloses the process of mixing metal salt(s) into **lens formulation** as a particulate (paragraphs 30-36; also see working examples). Therefore, Rothore fully anticipates the limitations of both Claims 1 and 28.

9. Regarding **Claims 2-11 and 14-16, ionized silver or other types of metal salt** can be used **with the claimed amount** (see various types of silver salt on paragraphs 24 and 28-29; see other metal salts on paragraph 34).

Regarding **Claims 12-13**, the claimed **particle size** of metal salt being less than 10 μm can be readily found on paragraph **30** at line 5.

Regarding **Claims 17-18 and 40-41**, the claimed **lens formulation** can be readily found on paragraph **35** at lines 6-8.

Regarding **Claims 19-21**, the claimed **molar solubility of the metal ion** can be readily found on paragraph **28** at lines 1-12.

Regarding **Claim 43**, the claimed **haze** being less than 150% can be readily found on paragraph **36** at line 4.

10. Claims 1-16, 19-21, 28 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Borowsky (US 4,576,453) or Barry et al. (EP 1,050,314 A1).

Regarding the limitation of two parent **Claim 1 (composition) and Claim 28 (process of making), each of Borowsky and Barry** has disclosed the preparation of contact lens by **adding metal ion from silver salt (AgX) or silver zeolite in the form as a solution into a hydrogel lens** so that metal ion can be stayed within gel matrix (see "453" at column 3, line 66 – column 4, line 9; column 4, line 44-56; also see Figure 4) (see "314" at abstract, line 1-8; column 6, line 6-8). According to the disclosure from "314", **such a contact lens having silver ion is found to be antimicrobial** (column 7, line 32-44; particularly see line 45).

Each reference is therefore **silent of the property as having the percent haze at less than about 200%**. In light of the fact that the prior art and the present invention recite **(a) substantially identical lens-type polymer and (b) inorganic-type metal salt** being able to stay within polymer matrix, a reasonable basis exists to believe that the products of the invention

inherently possess the same properties such as haze percent. Since PTO does not have proper means to conduct experiments, the burden of proof is now shifted to Applicants to show otherwise. *In re Best*, 195 USPQ 430 (CCPA 1977).

> It has been held that where applicant claims a composition in terms of function, property or characteristic where said function is not explicitly shown by the reference and where the examiner has explained why the function, property or characteristic is considered inherent in the prior art, it is appropriate for the examiner to make a rejection under both the applicable section of 35 USC 102 and 35 USC 103 such that the burden is placed upon the applicant to provide clear evidence that the respective compositions do in fact differ. *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Fitzgerald et al.*, 205 USPQ 594, 596 (CCPA 1980).

11. Regarding **Claims 2-11 and 14-16, ionized silver or other types of metal salt** can be used **with the claimed amount** (see "314" for various types of silver salt on paragraphs 26 and 33-34; see "453" at column 3, line 66-68; column 4, line 22).

Regarding **Claims 12-13**, the claimed **particle size** of metal salt being less than 10 μm is present since the silver halides carry photochemical properties and can be in the form of solution (see "453" at column 4, line 3-5; see "314" for using silver zeolite with a diameter of **2.5 microns** on paragraph **39** at line 8).

Regarding **Claims 19-21**, the claimed molar solubility of the metal ion is inherently present since the same salt as present application is used.

Regarding **Claim 43**, the claimed **haze** being less than 150% may be present with the same rational for rejection of Claim 1.

12. Claims 17-18 and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borowsky (US 4,576,453) or Barry et al. (EP 1,050,314 A1), **each individually in view of Rothore et al.** (USPG-PUB 2004/0151755 A1 with effective US filing date of December 21, 2000) **or McCabe et al.** (US 6,822,016 B2 with effective US filing date of September 10, 2001).

The above discussion of the disclosures of the prior art of Borowsky and Barry for Claims 1-16, 19-21, 28 and 43 of this office action is incorporated here by reference. The above discussion of the disclosures of the prior art of Rothore for Claims 1-21, 28, 40-41 and 43 of this office action is also incorporated here by reference. Regarding **Claims 17-18 and 40-41**, each of Borowsky and Barry is silent about (A) using the claimed lens formulation (for Claims 17 and 40-41) and using the claimed silver salt(s) (for Claim 18).

13. As discussed above for the rejection of Claims 17-18 and 40-41, the claimed **lens formulation** well known in the art have specifically been disclosed by **Rothore** (paragraph **35** at lines 6-8) or by **McCabe** et al. (column 21, line 19-22). As also discussed above for the rejection of Claims **2-11 and 14-16**, Rothore teaches that **ionized silver or other types of metal salt** can be used in making antimicrobial ophthalmic lens (see various types of silver salt on paragraphs 24 and 28-29; see other metal salts on paragraph 34). The advantage to use such a lens formulation is that such obtained lens is found to be in **optically clear quality** according to Rothore or McCabe's comparative results.

Therefore, one having ordinary skill in the art would have found it obvious to applied the claimed lens formulation along with the claimed silver salt so as to obtain antimicrobial ophthalmic lens in optically clear quality as taught by Rothore or McCabe. Additionally, more diversified products may be obtained.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicants' disclosure. The following references relate to **an antimicrobial ophthalmic lens** comprising a metal salt and the lens having a percent haze at less than 200%:

US Patent No. 5,520,910 to Hashimoto et al. (or its equivalent **WO 95/02617 to Hashimoto et al.**) only discloses an antimicrobial contact lens can be made from (A) **a polymer obtained by homo- or copolymerizing a phosphonium salt type vinyl monomer**, and (B) **a large quantity of an antimicrobial agent or a potent antimicrobial agent** (abstract, line 1-7; column 2, line 35-37). However, **metal salt is not disclosed or suggested**. **The claimed percent haze is not disclosed at all.** Therefore, Hashimoto fails to teach or fairly suggest the copolymers of present invention.

US Patent No. 6,815,074 B2 to Aguado et al. only discloses an ophthalmic antimicrobial contact lens useful for extended-wear periods can be made from (A) **a polymer obtained by polymerization of aoxyperm macromer and an ionoperm monomer** (abstract, line 1-10;

column 2, line 35-37). Although lens haze is discussed (column 20, line 22-62), **metal salt is not disclosed or suggested adding into the lens composition**. **The claimed percent haze is not disclosed at all.** Therefore, Aguado fails to teach or fairly suggest the copolymers of present invention.

15. Any inquiry concerning this communication or earlier communication from the examiner should be directed to **Dr. Henry S. Hu whose telephone number is (571) 272-1103**. The examiner can be reached on Monday through Friday from 9:00 AM –5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu, can be reached on (571) 272-1114. The **fax** number for the organization where this application or proceeding is assigned is **(571) 273-8300** for all regular communications. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H.H

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March 30, 2006

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